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Docket No. T-671-B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: A. Carrillo et al

Serial Number: 10/700,026

Filed: November 3, 2003

For: Aluminum-Zirconium Antiperspirant Salts
With Low M:Cl Ratio

Examiner: S. Dodson

Group Art Unit: 1616

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. 1.131

We, Angel L. Carrillo, Yan-Fei Shen and Richard Oryszczak, hereby declare that:

1. We are the inventors of the invention claimed in the above-identified application.
2. We made the invention and reduced it to practice in the United States prior to October 20, 2000, the filing date of US 6,375,937, as evidenced by the attached Exhibit.
3. The attached Exhibit is a copy of the first page of a memorandum dated February 29, 2000 entitled "Clinical Efficacy Studies: A Summary". This memorandum summarizes information on low M:Cl antiperspirant salts prepared and tested prior to that date. The chart provided in Table I demonstrates that antiperspirant salts identified by lot numbers 115-100, 116-126, 121-01, 115-99, 121-11 and 121-45 are aluminum-zirconium tetrachlorohydrate salts with M:Cl ratios of 0.92, 0.95, 0.96, 0.94, 0.92 and 0.9 respectively.

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4. The foregoing confirms that we had possession of the claimed invention prior to the effective date of US 6,375,937.

We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

7/14/2005
Date

7/18/2005
Date

7/19/2005
Date

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Date
2/29/00

Copies To

P. Angelone D. Callaghan

To

MAX5 Salt Team

T. Fluhler V. Murdock R. Oryszczak

From

A. Carrillo

S. Provancal J. Sane

Subject

Clinical Efficacy Studies: A Summary

Y-F. Shen A. Zlota

A report, issued on 3/30/99, entitled "Characteristics of the Aluminum Polymer Distribution and Solubility in alcohol of the Category I Al/Zr-gly Salts", discusses among other things salts with ML:CL ratios of ~0.90. These more acid salts demonstrated a higher peak 5 content in their HPLC profile. That is, the aluminum polymer size is reduced further from what is typically found in APEX. Both peaks 3 and 4 within the HPLC profile are reduced as peak 5 is increased. This transformation represents a reduction in aluminum polymer size. Such a salt with reduced aluminum polymer size (Lot # 115-100) had superior efficacy over APEX when both are separately formulated as aqueous solutions (APZR-878-0). The name MAX5 was selected to identify Al/Zr-gly salts characterized by low M:Cl ratio in the 0.90 to 0.95 range and a peak 5 content of over 50%.

This summary includes all clinic efficacy results as well as the process, chemical, and analytical characteristics associated with all the salts that were tested. Table I summarizes the testing to date.

TABLE I

Process, chemical, analytical, HPLC, and Efficacy Characteristics of MAX5 Salts

| TEST | LOT # | Type | Zr Source | Zr:Cl (Process) | ML:Cl | Al:Zr | 4:3 Ratio | %Peak 5 | Medium | Ave. + Pts. | Range | P-Value |
|--------|----------|------------------|-----------|------------------|-------|-------|-----------|---------|---------------------|-------------|------------|---------|
| A9916A | 115-88 | Primed-Octa | Low Na | 0.28 (Direct) | 0.94 | 10 | 0.41 | 53.9 | DIRO | 5.8 | 2.83-8.79 | 0.0001 |
| A078B | 115-100 | Primed-Tetra | Low Na | 0.45 (0.28+1.1) | 0.92 | 2 | 1.9 | 51.8 | WATER | 5.9 | 3.01-8.82 | 0.0001 |
| A9915A | 115-100 | Primed-Tetra | Low Na | 0.45 (0.28+1.1) | 0.92 | 2 | 1.9 | 51.8 | WATER | 4.59 | 1.77-7.41 | 0.002 |
| HT9905 | 115-100 | Primed-Tetra | Low Na | 0.45 (0.28+1.1) | 0.92 | 2 | 1.9 | 51.8 | DIRO | 8.72 | 6.15-11.3 | 0.0001 |
| A9925 | 116-128 | Primed-Tetra | Low Na | 0.44 (Direct) | 0.95 | 2.1 | 2.4 | 48.5 | WATER | 1.26 | <0-3.85 | 0.333 |
| A9925 | 121-01 | Primed-Tetra | ZOC | 0.44 (Direct) | 0.96 | 2.1 | 2.2 | 43 | WATER | 1.38 | <0-3.88 | 0.27 |
| A9927A | 115-99 | Not Primed-Tetra | Low Na | 0.47 (0.28+0.67) | 0.94 | 2 | 0.2 | 57.2 | WATER | 0.3 | <0-3.35 | 0.844 |
| A9932 | 121-10 | Primed-Octa | Low Na | 0.28 (Direct) | 0.94 | 10 | 0.46 | 53.7 | WATER | 4.16 | 0.49-7.83 | 0.025 |
| A9936A | 121-10* | Primed-Octa | Low Na | 0.28 (Direct) | 0.94 | 10 | 0.46 | 53.7 | CL. GEL | 15.93 | 9.14-22.76 | 0.0001 |
| A9932 | 121-11 | Primed-Tetra | Low Na | 0.45 (0.26+1.05) | 0.92 | 2 | 1.72 | 57.7 | WATER | 4.5 | <0-9.28 | 0.059 |
| A9934 | 121-11 | Primed-Tetra | Low Na | 0.45 (0.26+1.05) | 0.92 | 2 | 1.72 | 57.7 | SOLID | 3.85 | 0.88-7.04 | 0.012 |
| A9936B | 115-74** | Primed-Octa | Low Na | 0.28 (Direct) | 0.95 | 8.2 | 1.1 | 71.7 | WATER | 7.03 | 2.28-11.80 | 0.004 |
| A9938 | 121-45 | Primed-Tetra | Low Na | 0.44 (0.28+1.09) | 0.9 | 2.01 | 0.17 | 74.7 | SOLID | 2.05 | <0-4.83 | 0.161 |
| 10034 | 121-10 | Primed-Octa | Low Na | 0.28 (Direct) | 0.94 | 10 | 0.47 | 65.8 | Aged-45C CL. GEL | 13.3 | 7.74-18.96 | 0.000 |